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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/277,229	03/26/1999	MARTIN CITRON	A-581	3236

21069 7590 04/23/2002
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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/23/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/277,229

Applicant(s)

CITRON ET AL.

Examiner

Manjunath N Rao

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1652

DETAILED ACTION

In view of a new reference that has now become available, the finality of the rejection of the last Office action is withdrawn.

Claims 11-16 and 19 are still at issue and are present for examination. Claims 15-16 remain withdrawn from consideration as being drawn to non-elected subject matter. Claims 11-14 and 19 are now under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-12 and 19 recite the phrase “biologically active” which renders the claim indefinite. Examiner agrees that applicants define what is “biologically active beta-secretase” and Examiner believes that applicants intend that the biological activity they are referring to in the claims is the beta-secretase activity. However, the phrase “biologically active” can still mean any activity and what is not clear is the specific activity of the polypeptide. Amending the claim to recite “biologically active beta-secretase” would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Powell et al. (US 6,319,689 B1, 9-20-01, filed 1-20-98). Claims 11-14 are drawn to an isolated biologically active polypeptide selected from the group consisting of the polypeptides with SEQ ID NO:4, 5, and 6, or fragments thereof, or a polypeptide having 1-50 conservative amino acid changes, wherein the polypeptides are encoded by a polynucleotide sequence with SEQ ID NO:1, 2, 3 or fragments thereof, or polynucleotides with conservative changes of 1-50 in the nucleotides of SEQ ID NO:1, 2, 3. Powell et al. disclose a polynucleotide with SEQ ID NO:1 which encodes a polypeptide (with SEQ ID NO:2) which matches 100% with SEQ ID NO:4, and fragments corresponding to the biological activity and “mature” polypeptide corresponding to amino acid 45-501, thereby anticipating claims 11-14.

Art Unit: 1652

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (US 6,319,689 B1, 9-20-01, filed 1-20-98). Claim 19 in this instant application is drawn to a fusion protein comprising a polypeptide with beta-secretase activity selected from the group consisting of the polypeptides with SEQ ID NO:4, 5, and 6, or fragments thereof, or a polypeptide having 1-50 conservative amino acid changes. Powell et al. teach polypeptide which matches 100% with SEQ ID NO :4. Powell et al. also teach polynucleotides which encode the polypeptide with SEQ ID NO:4 and methods of making it using a vector and a host cell. However, the reference does not teach fusion protein comprising the polypeptide with SEQ ID NO:4,5 or 6.

It would have been obvious to one skilled in the art at the time the invention was made to use the teachings of Powell et al. and combine it with what is already well known in the art regarding the purification of recombinant polypeptides using 6X-His tag. Using such knowledge it would thus be obvious to one of ordinary skill in the art to subclone the polynucleotide encoding the polypeptide with SEQ IUD NO:4 provided by Powell et al. in to a vector comprising sequences which encode a 6X-His tag and express such a fusion polypeptide. One of ordinary skill in the art would be motivated to do this in order to purify recombinant polypeptide with SEQ ID NO:4 from culture extracts in one easy and quick step. One of ordinary skill in the art would have a reasonable expectation of success since Powell et al. provide the polynucleotide

Art Unit: 1652


and polypeptide sequence and the method is so well known in the art that commercial kit are available for doing the same, a reliable and time-tested method that has been used by a number of other inventors.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao Ph.D.
4/17/02


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PRIMARY EXAMINER
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1600 :